Benzoic Acid

Interim Registration Review Decision
Case Number 5107

September 2021

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I. INTRODUCTION

This document is the U.S. Environmental Protection Agency's (EPA or the Agency) Interim Registration Review Decision (ID) for benzoic acid (PC Code 009101, case 5107). In a registration review decision under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Agency determines whether a pesticide continues to meet FIFRA's registration standard.[1] Where appropriate, the Agency may issue an interim registration review decision before completing a registration review.[2] Among other things, the interim registration review decision may determine that new risk mitigation measures are necessary, lay out interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review.[3] For more information on benzoic acid, see EPA's public docket (EPA-HQ-OPP-2010-0692) at www.regulations.gov.

FIFRA[4] mandates the continuous review of existing pesticides. All pesticides distributed or sold in the United States must be registered by EPA based on scientific data showing that they will not cause unreasonable adverse effects to human health or to the environment when used as directed on product labeling. In 2006, the Agency began implementing the registration review program. EPA will review each registered pesticide every 15 years. Through the registration review program, the Agency intends to verify that all registered pesticides continue to meet the registration standard as the ability to assess and reduce risk evolves and as policies and practices change. By periodically re-evaluating pesticides as science, public policy, and pesticide-use practices change, the Agency ensures that the public can continue to use products in the marketplace that do not present unreasonable adverse effects. For more information on the registration review program, see http://www.epa.gov/pesticide-reevaluation.

The EPA is issuing an Interim Decision for benzoic acid so that it can move forward with aspects of the registration review that are complete. The Agency determined that no pollinator exposure and effects data are necessary to make a final registration review decision for benzoic acid. The Agency has evaluated risks to listed species and is making a "no effect" finding under the Endangered Species Act (ESA) for all listed species and designated critical habitat for such species and has therefore concluded that consultation with the Fish and Wildlife Service and the National Marine Fisheries Service under ESA section 7(a)(2) is not required. The Agency will complete endocrine screening for benzoic acid, pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA) 408(p), before completing this registration review.

This document is organized in five sections:

- *Introduction* (summarizing the ID);
- *Use and Usage* (discussing how and why benzoic acid is used);
- *Scientific Assessments* (summarizing EPA's risk and benefits assessments, updating or revising previous risk assessments, and discussing risk characterization);

[1] Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) § 3(g), 7 U.S.C. § 136a(g); 40 C.F.R. § 155.57.
[2] 40 C.F.R. §§ 155.56, 155.58.
[3] 40 C.F.R. § 155.56.
[4] As amended by the Food Quality Protection Act (FQPA) of 1996, Pub. L. No. 104-170, 110 Stat. 1489.

- *Interim Registration Review Decision* (presenting EPA's decision, regulatory rationale, and any mitigation measures to address risks of concern); and
- *Next Steps and Timeline* (discussing actions that registrants must take in response to the ID, if applicable).

A. Summary of Benzoic Acid Registration Review

On September 22, 2010, the Agency formally initiated registration review for benzoic acid with the opening of the registration review docket for the case.[5] The following summary highlights the docket opening and other significant milestones that have occurred thus far during the registration review of benzoic acid.

- December 22, 2010 – EPA posted the *Benzoic Acid Preliminary Work Plan* (PWP), to the public docket for a 60-day public comment period.

- May 2011 – EPA posted the *Benzoic Acid Final Work Plan* (FWP) to the public docket. No comments were received on the PWP.

- May 2013 – EPA issued a generic data call-in (GDCI) (GDCI-009101-1062) for benzoic acid to obtain data needed to conduct the registration review risk assessments. All data requirements were met.

- November 2020 – EPA posted the *Registration Review Draft Risk Assessment for Benzoic Acid (DRA)* to the public docket for a 60-day public comment period. No comments were received on the draft risk assessment.

- March 2021 – EPA posted the *Benzoic Acid Proposed Interim Registration Review Decision* (PID) to the public docket for a 60-day public comment period. No comments were received on the proposed interim decision.

- September 2021 – EPA completed an ID for benzoic acid and will announce its availability in the Federal Register.

II. USE AND USAGE

Benzoic acid was first registered in 1987, and all uses had been cancelled by 1989. Benzoic acid was subsequently re-registered in 2005 and is currently registered as an antimicrobial pesticide in two end-use products (EPs) used for the preservation of food-grade lubricating oils in commercial food-handling establishments. Currently, there are no registered agricultural pesticide uses of benzoic acid as an active ingredient.

Sodium benzoate (PC Code 009103), benzyl benzoate (PC Code 009501), and benzyl alcohol (PC Code 009502),which are similar to benzoic acid, may be combined with benzoic acid in the

[5] 40 C.F.R. § 155.50

subsequent cycles of registration review. This ID focuses solely on the use of benzoic acid as an active ingredient in antimicrobial pesticides.

III. SCIENTIFIC ASSESSMENTS

A. Human Health Risks

A summary of the Agency's human health risk assessment is presented below. The Agency used the most current science policies and risk assessment methodologies to prepare this risk assessment in support of the registration review of benzoic acid. For additional details on the human health assessment for benzoic acid, see the *Registration Review Draft Risk Assessment for Benzoic Acid*, which is available in EPA's public docket (EPA-HQ-OPP-2010-0692).

1. Risk Summary and Characterization

A summary of the Agency's human health risk assessment was presented in the PID. For the currently registered uses of benzoic acid, short- and intermediate-term dermal and inhalation exposures are likely during open-pour loading and mixing to occupational handlers. With personal protective equipment as specified on the label (e.g., gloves, etc.), exposures are expected to be minimal. Given the relatively low toxicity of benzoic acid, no adverse effects are expected from exposure to the currently registered antimicrobial products. Therefore, a quantitative occupational dermal and inhalation study was not performed. No risks of concern were identified for these exposures.

Dietary exposures to benzoic acid may occur from the use of benzoic acid as an active ingredient in food-contact lubricating oils as well as from the use of benzoic acid as an inert ingredient in pesticide formulations. Benzoic acid is not registered for uses that are likely to result in residues in drinking water. Exposures to residues of benzoic acid in or on food from the use of benzoic acid as an active ingredient in food-contact lubricating oils are expected to be minimal. Therefore, no quantitative dietary assessment was performed for benzoic acid in food-contact lubricating oils. Exposures to residues of benzoic acid in or on food from the use of benzoic acid as an inert ingredient in pesticide formulations are also expected to be minimal. Additionally, benzoic acid (1) has low toxicity (no effects at the highest dose tested, 1000 mg/kg/day); (2) is categorized by the U.S. Food and Drug Administration (FDA) as Generally Recognized as Safe (GRAS) up to 1000 ppm in food; (3) is naturally occurring; and (4) has a history of safe use via the oral route. Therefore, no risks of concern were identified from dietary exposures to benzoic acid from pesticidal sources.

Additionally, residential handler and non-occupational exposures are not expected; therefore, no risks of concern were identified for such exposures. Because dietary exposures are expected to be minimal and residential exposures are not expected, no risks of concern were identified for aggregate exposures. Finally, the EPA has not made a common mechanism of toxicity finding as to benzoic acid and any other substances, and benzoic acid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not

assumed that benzoic acid has a common mechanism of toxicity with other substances. Thus, no risks of concern were identified for cumulative exposures.

Since the PID, there have been no changes to the Agency's previous human health risk conclusions. For additional details on the human health assessment for benzoic acid, see the *Benzoic Acid Proposed Interim Registration Review Decision,* which is available in the public docket at www.regulations.gov under docket ID EPA-HQ-OPP-2010-0692.

2. Human Incidents

There are no human health incidents listed for benzoic acid in the Office of Pesticide Program's Incident Data System (IDS) covering the time period from July 13, 2016 to July 13, 2021. Based on the absence of benzoic acid incidents reported, EPA is not concerned that benzoic acid presents a risk at this time. The Agency intends to conduct ongoing human incident monitoring for benzoic acid and additional analyses if that monitoring indicates risks of concerns.

3. Tolerances

No tolerance or exemption from the requirement of a tolerance is required for the use of benzoic acid as a materials preservative in food-grade lubricating oils because EPA has concluded that when used as materials preservative in food-grade lubricating oils, the substance is not a "pesticide chemical" under the FFDCA. 21 U.S.C. § 321(q)(1)(B)(ii). Rather, benzoic acid is considered a food additive, subject to regulation by FDA. FDA has designated benzoic acid as GRAS when added directly to food at a level not to exceed 0.1% (1000 ppm) by weight of the food. 21 C.F.R. § 184.1021. Substances affirmed as GRAS for use in or on food may, under conditions of good manufacturing practice, "be safely used as components of articles that contact food." 21 C.F.R. § 174.5(d)(1). As described in the DRA, the maximum residue of benzoic acid on food that is expected to result from the use of benzoic acid as a materials preservative for food-grade lubricating oils is 10 ppm (significantly lower than the GRAS limit of 1,000 ppm).

EPA has established two exemptions from the requirement of a tolerance for benzoic acid as an inert ingredient in pesticide formulations under the FFDCA Section 408. For additional details for tolerances for benzoic acid, see the *Registration Review Proposed Interim Decision for Benzoic Acid*, which is available in EPA's public docket (EPA-HQ-OPP-2010-0692).

4. Human Health Data Needs

Although the benzoic acid toxicological database is incomplete, it is adequate for this interim decision based on the available toxicity studies and the low exposure potential for currently registered use patterns.

EPA lacks acceptable studies to support the requirements for prenatal developmental toxicity (OCSPP 870.3700) and for reproduction and fertility effects (OCSPP 870.3800). Although FDA considers sodium benzoate as generally recognized as safe (GRAS) by the oral route, this designation does not account for systemic effects that could occur via the inhalation route of

exposure. Despite the missing information, the Agency qualitatively assessed this active ingredient based on use patterns, long history of use, and relatively low hazard. The Agency notes that these studies were not required as part of GDCI-009101-1062 issued on May 14, 2013.

B. Ecological Risks

The Agency used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of benzoic acid. For additional details on the ecological assessment for benzoic acid, see *Registration Review Draft Risk Assessment (DRA) for Benzoic Acid* in EPA's public docket (EPA-HQ-OPP-2010-0692).

1. Risk Summary and Characterization

Benzoic acid is expected to be readily biodegradable in the environment with limited bioconcentration. Benzoic acid and its structurally-related compounds are practically non-toxic to birds, moderately toxic to freshwater fish, and practically non-toxic to freshwater invertebrates. Additionally, overall exposure is expected to be minimal in both terrestrial and aquatic habitats because of rapid degradation in the environment and limited potential for exposure from the currently registered uses.

There is no reasonable expectation for any registered use of benzoic acid in antimicrobial products to cause direct or indirect adverse effects to threatened and endangered species. No adverse modification of critical habitat is expected from any registered use of benzoic acid in antimicrobial products. Because of low hazard and exposure as described above, the EPA has made a "no effect" determination under ESA for all listed species and designated critical habitat for such species and has therefore concluded that consultation with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service under ESA § 7(a)(2) is not required.

2. Ecological Incidents

No benzoic acid ecological incidents were reported to the Office of Pesticide Program's IDS covering the time period from July 13, 2016 to July 13, 2021, when EPA last reviewed this database for incidents. Based on the lack of benzoic acid incidents, EPA is not concerned that benzoic acid presents a risk at this time. The Agency intends to conduct ongoing ecological incident monitoring for benzoic acid and additional analyses if that monitoring indicates risks of concern to nontarget organisms.

3. Ecological and Environmental Fate Data Needs

The ecological and environmental fate database for benzoic acid is considered complete.

IV. INTERIM REGISTRATION REVIEW DECISION

A. Risk Mitigation and Regulatory Rationale

No human health or ecological risks were identified for the current registered uses of benzoic acid. Therefore, no label changes or risk mitigation is being requested at this time.

B. Tolerance Actions

As discussed in Section III.A.3., no tolerance or exemption from the requirement of a tolerance for indirect food uses of benzoic acid is necessary because benzoic acid is intended for use as a materials preservative for food-grade lubricating oils, and as such is not considered a "pesticide chemical" for which a tolerance or exemption is necessary under the FFDCA. The necessary FDA clearances are in place, so no additional work is needed.

C. Interim Registration Review Decision

In accordance with 40 CFR §§ 155.56 and 155.58, the Agency is issuing this ID. Except for the Endocrine Disruptor Screening Program (EDSP), the Agency has made the following ID: (1) no additional data are required at this time; and (2) no changes to registrations or their labeling are being requested at this time.

In this ID, the Agency is making no human health or environmental safety findings associated with the EDSP screening of benzoic acid. The Agency's final registration review decision for benzoic acid will be dependent upon the result of the Agency's EDSP FFDCA § 408(p) determination. As covered in Section III.B.1., the Agency has made a "no effect" determination for the registered uses of benzoic acid under the ESA in this ID.

D. Data Requirements

The Agency does not anticipate calling-in additional data for benzoic acid at this time.

V. NEXT STEPS AND TIMELINE

In accordance with 40 CFR Sections 155.56 and 155.58, the Agency is issuing the *Benzoic Acid Interim Registration Review Decision*. A Federal Register Notice will announce the availability of this Interim Decision. The Agency determined that no pollinator exposure and effects data are necessary to make a final registration review decision for benzoic acid. The Agency has made a "no effect" determination under ESA for benzoic acid. The Agency's final registration review decision for benzoic acid will be dependent upon the result of the EDSP FFDCA section 408(p) determination.